The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARCO FALCIANI
and
SERGIO DUSCI

Appeal No. 2005-0925
Application 09/807,413

HEARD: May 4, 2005

Before FRANKFORT, MCQUADE and NASE, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 6 through 25, all of the claims remaining in the application. Claims 1 through 5 have been canceled.

Appellants' invention relates to a bag of polyolefin construction used to preserve and transport a product in powder form under sterile conditions and to enable a liquid solvent to be introduced into the bag to form therein a solution of said sterile product having a predetermined concentration. The invention also addresses a method for preparing solutions with predetermined concentrations of soluble sterile product in powder form enclosed and sealed within a sterile bag constructed of flexible polyolefin. Independent claims 6, 9, 12, 14, 16, 20 and 23 are representative of the subject matter on appeal and a copy of those claims can be found in the Appendix to appellants' brief.

The prior art references relied upon by the examiner in rejecting the appealed claims are:

Gilford	3,647,386	Mar. 7, 1972
Sutryn et al. (Sutryn)	4,550,825	Nov. 5, 1985
Herbert et al. (Herbert)	5,257,986	Nov. 2, 1993

Claims 6 through 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable Sutryn or Herbert in view of Gilford.

Rather than attempt to reiterate the examiner's commentary with regard to the above-noted rejections and the conflicting viewpoints advanced by the examiner and appellants regarding those rejections, we make reference to the examiner's answer (mailed July 28, 2004) for the reasoning in support of the rejections, and to appellants' brief (filed May 24, 2004) and reply brief (filed August 26, 2004) for the arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by appellants and the examiner. As a consequence of our review, we have made the determinations which follow.

Claims 6 and 9 read as follows:

6. A bag for preserving and transporting a soluble sterile product in powder form and for reconstituting in the bag a ready to use solution with a predetermined concentration of the sterile product,

the bag being of polyolefin construction;

the bag being hermetically sealed at its periphery to define a sterile closed space and having at least one port also of polyolefin construction defining a passageway having two ends that open inside and respectively outside the bag, the passage-way being closed by a pierceable membrane for introduction of a solvent into the bag and respectively for withdrawal of the ready to use solution from the bag,

wherein the bag contains an amount of the sterile product in powder form adapted to give with the solvent and within the bag the reconstituted ready to use solution only partially filling a capacity of the bag, and

wherein the at least one port of the bag is plugged by a plug, the plug configured to receive a syringe port through the plug to remove the reconstituted ready to use solution from the bag.

9. A sealed bag constructed of flexible polyolefin material and configured to contain a ready to use solution reconstituted in the sealed bag by introducing within the sealed bag originally containing a dosed amount of a soluble sterile product in powder form an amount of solvent adapted to give the ready to use solution a desired concentration of the sterile product, wherein a capacity of the sealed bag is larger than a volume of the ready to use solution after the ready to use solution is reconstituted in the sealed bag.

These claims set forth, in somewhat different language, a sealed bag of polyolefin construction wherein the sealed bag contains an amount of a sterile product in powder form adapted to give with a solvent, to be introduced into the bag at a later

time, a reconstituted ready to use solution with a predetermined concentration of the sterile product and only partially filling a capacity of the bag. By contrast, the patents to Sutryn and Herbert both disclose a composite package or bag assembly wherein the bag (10 of Sutryn and 3 of Herbert) comprises a separate entity or compartment containing a predetermined amount of a liquid diluent adapted to be mixed with a dry medicament powder held in a second container or compartment (28 of Sutryn and 2 of Herbert) carried by the bag and capable of communicating with the interior of the bag so that the dry medicament powder can be introduced into the bag and mixed with the liquid diluent to form a ready to use solution having a predetermined concentration and only partially filling a capacity of the bag.

Thus, while each of the article claims on appeal defines a sealed bag for preserving and transporting a soluble sterile product in powder form contained within the bag and for reconstituting in the bag a ready to use solution with a predetermined concentration of the sterile product, and requires the bag to be constructed and configured to allow introduction of

an amount of solvent for reconstituting the ready to use solution within the bag, the prior art patents to Sutryn and Herbert applied by the examiner have no disclosure or teaching of such a bag. In both Sutryn and Herbert the sterile powder product (40 of Sutryn and 17 of Herbert) is carried in a separate compartment joined to the bag and the bag itself already contains a predetermined amount of liquid diluent.

Although the end result of a bag containing a ready to use solution having a predetermined concentration and only partially filling a capacity of the bag may be generally the same in Sutryn, Herbert and appellants' invention, the bag from which and in which the final solution is ultimately formed is entirely different. Independent claims 6 and 9 read on the bag seen in Figures 1-3 of the present application, wherein the sealed bag contains a measured amount of soluble sterile product (10) in powder form and wherein the bag serves as a means for preserving and transporting the soluble sterile product in powder form and for subsequently permitting the powdered product to be reconstituted in the bag by the addition of a measured amount of

liquid into the bag to provide a ready to use solution with a predetermined concentration of the sterile product. No such bag is disclosed, taught or suggested in Sutryn or Herbert.

Like appellant, we additionally find no teaching in the blood processing bag of Gilford that would overcome the deficiencies of Sutryn and Herbert noted above. Accordingly, the examiner's rejection of claims 6 and 9 under 35 U.S.C. § 103(a), and of claims 7, 8, 10 and 11 which depend therefrom, will not be sustained.

Claims 12 through 25 on appeal are method claims generally addressing a method for preparing a solution with a predetermined concentration of soluble sterile product originally in powder form enclosed and sealed within a sterile bag constructed of flexible polyolefin and a method of using such a prepared solution from the bag. Independent method claims 12, 14, 16 and 20 set forth the step of

> feeding into the bag, containing a dosed amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, an amount

> of solvent adapted to reconstitute a ready to use solution with a desired concentration of the sterile product.

Each of these claims, in one form or another, also requires that the fed amount of solvent be less than a capacity of the bag. Independent claim 23 has a similar "feeding" step and likewise requires that the fed amount of solvent be less than a capacity of the bag "such that a capacity of the bag is larger than a volume of the ready to use solution after the ready to use solution is reconstituted in the bag."

As noted by appellants in their brief, the examiner's "shotgun" rejection of claims 6 through 25, makes little or no attempt to separately address method claims 12 through 25, and utterly fails to provide any explanation as to why it would have been obvious to one of ordinary skill in the art at the time of appellants' invention, having a bag like that seen in either Sutryn or Herbert, to perform a method like any of those claimed by appellants. This is especially true since the bags in both Sutryn and Herbert already contain an amount of solvent or liquid

diluent necessary to reconstitute a ready to use solution with a predetermined concentration of the sterile product when the product in powder form is subsequently introduced into the bag containing the liquid diluent. Thus, no "feeding" step like that set forth in appellants' method claims on appeal is needed in either Sutryn or Herbert and clearly would not have been obvious to one of ordinary skill in the art at the time of appellants' invention.

Regarding the examiner's assertion that Herbert (col. 2, lines 37-61) provides a teaching of an order in which the components are introduced into the bag, and specifically suggests that the powder product is "first" and that the aqueous solution is then filled, we find nothing of the sort taught or suggested in Herbert. It appears to us from a complete reading of column 2, lines 37-66 of Herbert that the first container or chamber (2) is formed, closed and radiation sterilized, and that the aqueous solution is then filled into the second chamber (bag 3) which is also closed and subjected to heat sterilization, with the closed first container (2) joined to the bag "being poststerilized at

the same time." It is then indicated that "[t]he first chamber can subsequently be opened, with the sterile conditions being maintained, and a powdery medicament may be filled under sterile conditions, e.g., laminar flow, into the first chamber which is then closed by a sterile plug." Thus, it appears that the filling of the powder product or medicament (17) into the first chamber (2) is essentially the last step that takes place in the process of forming the composite package or bag assembly of Herbert, not the "first" as the examiner contends.

Moreover, we again find that the examiner's use of the blood processing bag of Gilford provides no teaching, suggestion or incentive that would overcome the deficiencies of Sutryn and Herbert noted above. Thus, based on the foregoing, we will not sustain the examiner's rejection of claims 12 through 25 under 35 U.S.C. § 103(a).

To summarize: the rejections under 35 U.S.C. § 103(a) as posited by the examiner have not been sustained. Thus, the

decision of the examiner rejecting claims 6 through 25 of the present application is reversed.

In addition to the foregoing, we find it necessary to REMAND this application to the examiner for consideration of the following issues:

1) Review of U.S. Patent No. 5,484,431 cited in the International Search Report for this application before it entered into the National Stage under 35 U.S.C. § 371. This patent appears to show a bag generally like that of the present application which contains a powder product and multiple ports into the bag which provide for the addition of water to produce a reconstituted solution in the bag and also allow for dispensing of the reconstituted solution.

2) The examiner should also review U.S. Patent Nos. 3,306,563, 3,648,697, 4,863,454 and 5,385,564, each of which appears to show a bag originally containing a sterile powdered

product, e.g., a medicament or nutritional supplement, to which a fluid is added for reconstituting a solution in the bag.

3) The examiner should also recognize that the claims on appeal are not limited to a reconstituted solution to be used in the medical arts, but is more broadly recited so as to encompass a food item or beverage product in powder form, such as the dehydrated food and beverage products (e.g., TANG) that were used by NASA astronauts while in the weightless environment of space. Thus, the examiner should consider a search in Class 426 or other appropriate areas and look to prior art such as U.S. Patent No. 3,602,273 which shows a fluid dispenser, known as an "Apollo Water Dispenser," for dispensing water through a one way valve into a flexible film package containing dehydrated food so as to provide a reconstituted substance or solution in the bag.

This application, by virtue of its "special" status, requires immediate action, see MPEP § 708.01 (Eighth Edition, Rev. 2, May 2004), item (D).

REVERSED AND REMANDED

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